

Texas Department of State Health Services

Texas Vaccine Providers Webinar

Tuesday, March 8, 2022

Disclaimer

The information presented today is based on CDC's recent guidance and MAY change.

Tuesday, March 8, 2022

Discussion Topics

Opening Remarks – Tony Aragon, MS

COVID-19 Vaccine Panel Q&A – Cheryl Garcia; Jennifer Moore; Saroj Rai

Live Q&A

COVID-19 Vaccine Product Ordering Updates – Oscar Paz

COVID-19 ImmTrac2 Reporting – Paul Spock

Live Q&A



Texas Department of State Health Services

Opening Remarks

Tony Aragon, MS

Director | Immunization Unit

COVID-19 Vaccine Panel Q&A

Saroj Rai, PhD, MPH

Senior Scientific Advisor | Office of Chief State Epidemiologist

Jennifer Moore, BSN, RN

Nurse IV – Operations Team | Immunization Unit

Cheryl Garcia, BSN, RN

Contract Nurse III | Immunization Unit

Audience Poll

Select the correct answer choice:

A 7-year-old child who is 5'10" and weighs 170 pounds presents for the COVID-19 vaccine. Which COVID-19 vaccine presentation should be administered?

- A. Pfizer COVID-19 vaccine (orange cap)
- B. Pfizer COVID-19 vaccine (purple cap)
- C. Pfizer COVID-19 vaccine (gray cap)
- D. Any of the above would be appropriate in this instance.

Pfizer COVID-19 Vaccine Formulations

Pfizer COVID-19 Vaccine	Pediatric Formulation ¹ (100 doses/pack)	Adolescent/Adult Formulation ¹ (300 dose/pack)	Adolescent/Adult Formulation ¹ (1,170 dose/pack)	
Age Group	5 to 11 years	12 years and older	12 years and older	
Vial Cap Color	ORANGE	ORANGE GRAY		
Dilution Needed	YES	NO	YES	
Dose (after dilution)	0.2 mL (10 mcg)	0.3 mL (30 mcg)	0.3 mL (30 mcg)	
Total Doses per Vial	10 doses per vial (after dilution)	6 doses Per Vial	6 doses per vial (after dilution)	
Storage Options				
Thermal Shipper	x	x	30 Days ²	
Ultra-Low Temperature Freezer	9 months	9 months	9 months	
Freezer	X	X	2 weeks	
Refrigerator	10 weeks	10 Weeks	1 month	
Room Temperature	12 hours prior to first puncture	12 hours prior to first puncture	2 hours prior to dilution	
After First Puncture	Discard after 12 hours	Discard after 12 hours	Discard after 6 hours	

- 1. Orange cap vial cannot be used in individuals 12 years of age and older. Purple cap and Gray Cap vials cannot be used for children younger than 12 years.
- 2. Dry ice replenishment every 5 days



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Question

An 11-year-old individual comes in to receive their 1st dose of Pfizer COVID-19 vaccine. They return a month later and are now 12 years old. Which vaccine product do you administer as the second dose?

Answer

- Children should receive the ageappropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.
- If a child turns 12 years old between their first and second dose, they should receive the age-appropriate 30 µg Pfizer-COVID-19 Vaccine (purple or gray cap) formulation for their second dose
- <u>CDC Interim Clinical Recommendations</u> <u>Children</u>

	General Population (Ages 5 - 64 Years) ^a			
	Number of Doses in Primary Series	Number of Booster Doses	Interval between 1 st Dose and 2 nd Dose	Interval between 2 nd Dose and Booster Dose ^b
Pfizer (5-11 years) (orange cap)	2	NA	3 weeks ^d	NA
Pfizer (≥12 years) (purple → gray cap)	2	1	3-8 weeks ^a	≥ 5 months
Moderna (≥18 years)	2	1	4-8 weeks ^a	≥ 5 months
J&J's Janssen (<u>></u> 18 years) ^c	1	1	NA	≥ 2 months (between dose 1 and booster dose)

a: An 8-week interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Pfizer; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease: COVID-19 vaccination schedule for the primary series in the general population

d: Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.





b: Booster doses may be mix and match for individuals >18 yrs, mRNA vaccines are preferred: Booster dose may be mix and match vaccine

c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine



We have a patient who recently came to the U.S. from England. They received 2 doses of Novavax. They are considered moderately to severely immunocompromised. What is the next step in their vaccination process?

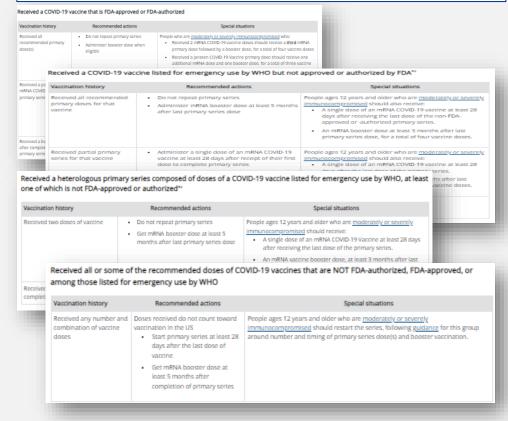
Answer

They should receive:

- A single dose of an mRNA COVID-19 vaccine at least 28 days after receiving the last dose of the non-FDA-approved or —authorized primary series.
- An mRNA booster dose at least 3 months after last primary series dose, for a total of four vaccine doses.



Appendix E. People who received COVID-19 vaccine outside the United States



https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#:~:text=as%20a%20resource.-,Appendix%20E.%20People%20who%20received%20COVID%2D19%20vaccine%20utside%20the%20United%20States,-The%20recommendations%20for



323368

Question

Our 16-year-old patient received 2 doses of Moderna. Can they receive a booster?

Answer

If Moderna COVID-19 Vaccine administered:

- As the first dose, administer the age-appropriate Pfizer-BioNTech COVID-19 Vaccine as the second dose at least 28 days after the Moderna vaccine dose. Administer a Pfizer BioNTech booster dose at least 5 months later.
- As the second dose, or as both the first and second dose, the primary series is complete. Administer a Pfizer-BioNTech booster dose at least 5 months later.
- As a booster dose, no more doses are indicated. The recipient is up to date.

	General Population (Ages 5 - 64 Years) ^a			
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b: Booster doses may be mix and match for individuals >18 yrs, mRNA vaccines are preferred: Booster dose may be mix-and-match vaccines



c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine

d: Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.



Question

A patient was diagnosed with the COVID-19. They received passive antibody therapy on day 4. They are at your office on day 10 currently asymptomatic. Can they receive their first dose of COVID-19 vaccine?

Answer

- People with known SARS-COV-2 infection should defer any COVID-19 vaccination, including booster vaccination, at least until recovery from the acute illness.
- People who previously received antibody products (anti SARS-COV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis, can be vaccinated at any time.

	General Population (Ages 5 - 64 Years) ^a			
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b: Booster doses may be mix and match for individuals >18 yrs, mRNA vaccines are preferred: Booster dose may be mix-and-match vaccines

c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine

d: Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.





COVID-19 Vaccination Recommendations

Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

COVID-19 Vaccination History	And	Then	Next Dose Due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a second dose (an additional mRNA vaccine) at least 28 days after the 1st dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Administer a booster dose at least 2 months after the 2nd dose.* • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL)*	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL)*	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)	Vaccination series complete; no additional vaccinations needed.

^{*}mRNA vaccines are preferred.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#appendix-b



^{*}When reviewing vaccination history, doses of the Moderna COVID-19 Vaccine received prior to February 7, 2022 should be considered to have been the booster dosage (0.25 mL; 50 mcg).



My patient is an organ recipient and received one dose of J&J COVID-19 vaccine. Are there additional doses the patient should receive?

Answer

Administer a second dose (an additional mRNA vaccine) at least 28 days after the 1st dose.

Pfizer: 0.3mL, or

Moderna 0.5mL

Administer a booster dose at least 2 months after the 2nd dose.*

Pfizer: 0.3mL, or

Moderna 0.25mL, or

Janssen: 0.5mL (mRNA is preferred over Janssen)



Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

Vaccination History	And	Then	Next Dose Due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a second dose (an additional mRNA vaccine) at least 28 days after the 1st dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Administer a booster dose a least 2 months after the 2nd dose.* • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRN/is preferred over Janssen)
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL)*	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL)*	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)	Vaccination series complete no additional vaccinations needed.

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Question

My 54-year-old patient receiving long term steroid treatment receives both a primary series and a booster dose of J&J COVID-19 vaccine. Can we administer an additional dose and what vaccine(s) do we use?

Answer

Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose.

Pfizer: 0.3mL, or

Moderna 0.5mL

Vaccination series complete; no additional vaccinations needed.



Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

History	And	Then	Next Dose Due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a second dose (an additional mRNA vaccine) at least 28 days after the 1st dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Administer a booster dose least 2 months after the 2n dose.* • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRN is preferred over Janssen)
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complet no additional vaccinations needed.
'	and 1 dose of an mRNA COVID-19 Vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL)*	Administer a time dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL)*	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)	Vaccination series complet no additional vaccinations needed.

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Question

My patient with HIV received a primary dose of J&J COVID-19 vaccine and a booster dose of Pfizer. Can we administer an additional dose and what vaccine(s) do we use?

Answer

Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose.

• Pfizer: 0.3mL, or

Moderna 0.5mL

Vaccination series complete; no additional vaccinations needed.



Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

COVID-19 Vaccination History	And	Then	Next Dose Due
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My patient, with advanced renal disease, received 1 dose of J&J COVID-19 vaccine and an additional dose of Moderna (0.5mL). What do I do next?

Answer

Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose.

- Pfizer: 0.3mL, or
- Moderna 0.25mL, or
- Janssen: 0.5mL (mRNA is preferred over Janssen)

Vaccination series complete; no additional vaccinations needed.



Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

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Question

Does the provider have to restart the series when their client comes in late for their 2nd dose or booster?

Answer

- Do not repeat dose. There is no maximum interval.
- This deviation from CDC guidance does not require VAERS reporting.



	General Population (Ages 5 - 64 Years) ^a			
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b: Booster doses may be mix and match for individuals >18 yrs, mRNA vaccines are preferred: Booster dose may be mix-and-match vaccine

c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine

d: Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.



Question

Do I need to observe patients after vaccination?

Answer

Yes. CDC recommends the following <u>observation</u> periods after COVID-19 vaccination:

30 minutes

- People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen vaccine)
- History of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
- History of an immediate allergic reaction of any severity to non-COVID vaccines or injectable therapies
- History of anaphylaxis due to any cause
- **15 minutes:** All other people

Observation periods following vaccination to monitor for allergic reactions

CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes:
 - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen vaccine)
 - History of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
 - $\circ \ \ \text{History of an immediate allergic reaction of any severity to non-COVID-19} \ \text{vaccines or injectable therapies}$
 - o History of anaphylaxis due to any cause
- 15 minutes: All other people

Appendix%20B.%20Guidance



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Question

What side effects might occur following vaccination?

Answer

Before vaccination, counsel patients about expected local and systemic side effects. Common side effects include:

- Local reactions
- Systemic reactions

Patient counseling

Pre-vaccination counseling

The vaccine-specific Fact Sheet for Recipients and Caregivers (Pfizer-BioNTech, Moderna Janssen Janssen) should be provided to all vaccine recipients, parents or guardians, and caregivers (when relevant) before vaccination with any currently FDA-approved or FDA-authorized COVID-19 vaccine. They should be informed that mRNA vaccines are preferred over the Janssen COVID-19 Vaccine and that there is a risk of thrombosis with thrombocytopenia syndrome (TTS) following receipt of the Janssen COVID-19 Vaccine. Those who elect to receive the Janssen COVID-19 Vaccine should be informed about the risk and symptoms of TTS that can occur (typically in the 2 weeks after vaccination), as well as the need to seek immediate medical care should symptoms develop.

Potential for local and systemic reactions

Before vaccination, providers should counsel COVID-19 vaccine recipients, parents, or guardians about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination reactions. Localized axillary lymphadenopathy⁴ on the same side as the vaccinated arm has been observed following vaccination with mRNA COVID-19 vaccines.

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines to COVID-19 vaccine recipients before vaccination to prevent allergic reactions is not generally recommended. However, while antihistamines will not prevent anaphylaxis, some experts advise antihistamine use as a means of preventing milder allergic reactions in patients who might be at higher risk for allergic reactions.

Management of post-COVID-19-vaccination symptoms

For all currently FDA-approved or FDA-authorized COVID-19 vaccines, antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate; these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms. However, in general, aspirin is **not recommended** for use in children and adolescents ages 17 years and younger as an antipyretic or analgesic due to the risk of Reye's syndrome.



Question

I have a patient seeking vaccination at the end of the clinical day, but I would have to puncture a new vaccine vial. I am concerned I will have to waste doses of vaccine. Should I ask the person to return another time for vaccination?

Answer

No. Never miss an opportunity to vaccinate every eligible person and limit wastage can be found here: <u>Identification, Disposal, and Reporting of COVID-19</u> <u>Vaccine Wastage</u>.

As more Americans get vaccinated, COVID-19 cases, outbreaks, hospitalizations, and deaths would be expected to decline significantly. In the efforts to expand <u>access to COVID-19 vaccines</u>, providers should take every opportunity to **vaccinate all eligible persons** with a <u>primary series or booster dose</u>.

However, as the rate of vaccine administration slows, the likelihood of leaving unused doses in a vial may increase, even when providers continue to follow best practices to use every dose possible.

CDC develops policies and procedures to help jurisdictions and planners <u>handle COVID-19 vaccine waste</u>. Jurisdictions should review and update existing vaccination plans to implement these vaccine wastage practices. Due to existing regulatory requirements, jurisdictions may need to develop standard operating procedures (SOPs) for medical waste disposal **in accordance with state law and local practice**.

https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf https://www.cdc.gov/vaccines/covid-19/hcp/wastage-operationalsummary.html#:~:text=Identifying%2C%20Disposing%2C%20and%20Reporting%20COVID%2D1 9%20Vaccine%20Wastage



Question

I think a vaccination administration error occurred. What should I do and how do I report this error?

Answer

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the <u>state immunization program</u> and/or <u>immunization information system (IIS)</u> to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise
 indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—
 even those not associated with an adverse event—to VAERS. To file an electronic report, please see
 the VAERS website.
- Determine how the error occurred and implement strategies to prevent it from happening again. A
 discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of
 Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Additional resources
 can be found on CDC's vaccine administration web page, including a job aid for preventing errors.
- Follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine and formulation. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes).
 - For doses recommended to be repeated, some experts suggest further delaying the repeated dose for 8 weeks after the
 invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19
 vaccine, particularly in groups at increased risk for myocarditis (e.g., 12-29 year old males). Individual risk for COVID-19
 and the likelihood for an adverse event following COVID-19 vaccination should be taken into consideration when
 recommending a longer interval.

Appendix A. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm.

The FDA-issued Fact Sheet for Healthcare Providers Administering Vaccines [2] should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A

Question

Do COVID-19 vaccine providers need to upload temperature logs as a requirement of the COVID-19 Vaccine Program?

Answer

COVID-19 vaccine providers are <u>not</u> required to upload temperature logs in VAOS. Uploading temperature logs is a requirement for TVFC/ASN programs but is not a requirement for the COVID-19 vaccine program.

However, COVID-19 vaccine providers are required to submit a current certificate of calibration for vaccine data loggers to COVID19VacEnroll@dshs.texas.gov.



COVID-19 Vaccine Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 1-15 Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information. If the temperature is out of range, Option 1: Minimum/Maximum (Min/Max) **Option 2: Current Temperature** TAKE ACTION! Temperatures (preferred) If the DDL does not display min/max temperatures, Most DDLs display minimum and maximum check and record the current temperature at the start Do NOT discard the vaccine. and end of the workday temperatures. Check and record the min/max Label the vaccine "Do Not Use." temperatures at the start of each workday. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature Document these temperatures in the min/max Complete the Vaccine Troubleshooting Record. under the appropriate day of the month. temperature row under the appropriate date. Contact the manufacturer to determine under 3. Review the continuous DDL temperature data daily. what conditions (refrigerated) to store the vaccine as quickly as possible. Month **Facility Name** O Day of the month 15 Time Staff initials Min/max AM PM AM Time Staff initials 2°C 3°C 4°C 5°C 6°C 7°C

8°C

Vaccine Manufacturer Resources



Medical Information

Phone: 800-438-1985

Email:

<u>PfizerMedicalInformation@pfizer.com</u>

Website: <u>www.PfizerMedInfo.com</u>

moderna

Medical Information

Phone: 866-663-3762

Email: MedInfo@modernatx.com

Temperature excursion related

questions:

Email: excursions@modernatx.com

Janssen J

Medical Information

Phone: 800-565-4008

Temperature excursion related questions:

Email:

JSCCOVIDTEMPEXCURSION@its.jnj.com

COVID-19 Vaccine Clinical Reminders

Cheryl Garcia, BSN, RN

Contract Nurse III | Immunization Unit

COVID-19 Vaccine Administration Guidance

4-Day Grace Period

Doses of COVID-19 vaccine administered **up to 4 days before the minimum interval**, known as the 4-day grace period, are considered valid. If a dose is administered prior to the 4-day grace period and is a:

- Primary series dose, it **should** be repeated; the repeat dose should be spaced from the date of the dose given in error by the recommended minimum interval.
- Booster dose; it should **not** be repeated (see <u>Appendix A</u> for more details).



Doses administered at any time after the recommended interval are valid.



Self-Attestation to Immunocompromised Status

People can **self-attest** to their moderately to severely **immunocompromised status** and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators **should not deny** COVID-19 vaccination to a person due to lack of documentation.



When to Restart COVID-19 Vaccine Primary Series

The only time CDC recommends restarting a series regarding COVID-19 vaccines is if the individual was vaccinated with a COVID-19 vaccine that is NOT FDA-authorized, FDA-approved, or among those listed for emergency use by WHO. No other situation currently exists indicating a series should be restarted.

Vaccination history	Recommended actions	Special situations
Received any number and combination of vaccine doses	Doses received do not count toward vaccination in the US • Start primary series at least 28 days after the last dose of vaccine • Get mRNA booster dose at least 5 months after completion of primary series	People ages 12 years and older who are <u>moderately or severely</u> <u>immunocompromised</u> should restart the series, following <u>guidance</u> for this group around number and timing of primary series dose(s) and booster vaccination.

Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorized, FDA-approved, or

CDC Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html? https://www.cdc.gov/vaccines/2Fcovid-19/2Finfo-by-product%2Fclinical-considerations.html https://www.cdc.gov/vaccines%2Fcovid-19/2Finfo-by-product%2Fclinical-considerations.html https://www.cdc.gov/vaccines%2Fcovid-19/2Finfo-by-product%2Fclinical-considerations.html https://www.cdc.gov/vaccines%2Fcovid-19/2Finfo-by-product%2Fclinical-considerations.html <a href="https://www.cdc.gov/vaccines%2Fcovid-19/2Finfo-by-product%2Fcovid-19/2Finfo-by-produ

,Received%20all%20or%20some%20of%20the%20recommended%20doses%20of%20COVID%2D19%20vaccines%20that%20are%20NOT%20FDA%2Dauthorized%2C%20FDA%2Dapproved%2C%20or%20among%2 0those%20listed%20for%20emergency%20use%20by%20WHO,-Received%20all%20or

DSHS COVID-19 Vaccination Schedule Infographic: https://www.dshs.texas.gov/immunize/covid19/COVID-19-Vaccine-Schedule.pdf

Live Q&A



COVID-19 Vaccine Product Ordering Updates

Oscar Paz

Program Specialist V | Immunization Unit

Confirm Pfizer COVID- 19 Vaccine Expiry Date

To check expiration dates for Pfizer COVID-19 vaccine (orange, gray, or purple cap), providers can visit this webpage and select Expiry Information.

Providers can also confirm Pfizer COVID-19 vaccine expiration dates by contacting Pfizer by email at

<u>pfizermedicalinformation@pfizer.com</u> or by phone at **800-438-1985**.

THREE VACCINE PRESENTATIONS ARE AVAILABLE

Three vaccine presentations are available with different preparation and storage guidelines.

As of 12/16/21, Ages 12 years and older, DO NOT DILUTE (Gray Cap) and 5 through 11 years, DILUTE BEFORE USE (Orange Cap) have extended expiry from 6 months to 9 months from the date of manufacture printed on the vial and cartons in an Ultra-Low-Temperature (ULT) Freezer -90°C to -60°C (-130°F to -76°F).

Please see the table below and click the following button for expiry information:

Note: Pfizer gray cap COVID-19 vaccines and Pfizer orange cap COVID-19 vaccines do NOT have an expiration printed on the vial. Instead, each vial has the lot number **and date of manufacture printed on the label.**

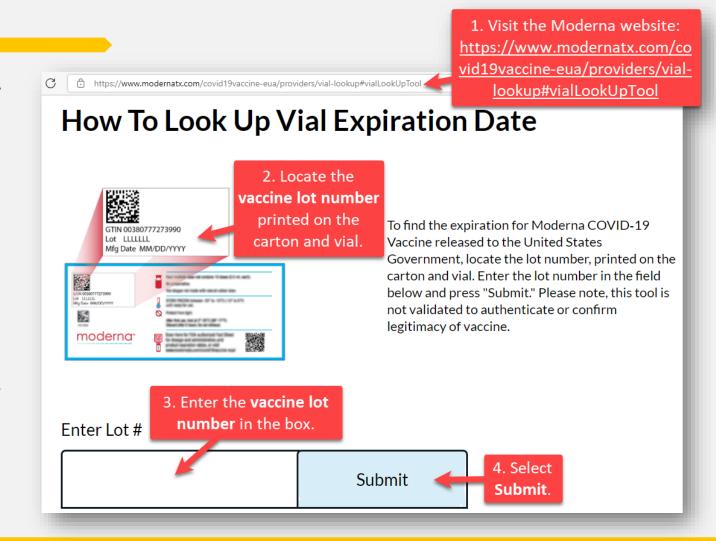
Children ages 5 through 11 years old should only be vaccinated with the Ages 5 th

Confirm Moderna COVID-19 Vaccine Expiry Date

The steps on the right outline how you can check the expiration date for your Moderna COVID-19 Vaccine.

For more details, providers can visit:

https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup#vialLookUpTool.



Confirm Janssen/J&J COVID-19 Vaccine Expiry Date

The expiration date for Janssen/J&J COVID-19 vaccine can be obtained in 3 different ways:

- By entering the lot number (from the carton or vial) from the carton or vial using the website www.vaxcheck.jnj
- By calling J&J's automated response system at 1-800-565-4008. (This process should take less than one minute to complete.)
- By scanning the QR code or the Data Matrix code using a smartphone camera.

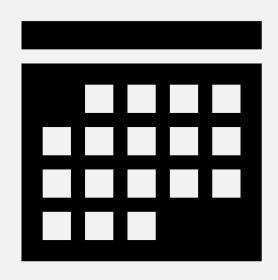


Janssen/J&J COVID-19 Vaccine Shelf-Life Extension

The FDA announced the approval of a shelf life extension for the Johnson & Johnson's Janssen COVID-19 vaccine for an additional three months. The shelf life of this vaccine has been updated from 6 months to 9 months. This shelf life extension applies to all inventory dated to expire on March 7, 2022 or later.

Vaccine dated prior to March 7, 2022 should be disposed of according to state and local regulation and reported as waste.

Please check the manufacturer's website to obtain the most up-to-date expiration dates for the COVID-19 vaccines you have on hand: https://vaxcheck.jnj/



VAOS Account Suspended? Contact Us!

If your VAOS account has been suspended and you are getting your order requests automatically denied, please contact the correct channel so that your account can be unlocked. Be sure to include an up-to-date data logger certificate of calibration in your email.

If you are a COVID-19 vaccine provider only, please send your information to VacEnroll: <u>COVID19VacEnroll@dshs.texas.gov</u>



If you are a COVID-19 vaccine provider and a TVFC/ASN provider, please send your information to the VacCallCenter:

VacCallCenter@dshs.texas.gov



COVID-19 Vaccine ImmTrac2 Reporting

Paul Spock

Training Coordinator – Texas Immunization Registry | Immunization Unit

ImmTrac2 Resources

To view ImmTrac2 training webinars and videos, providers can visit the ImmTrac2 User Training webpage at:

https://www.dshs.texas.gov/immunize/immtrac/User-Training/

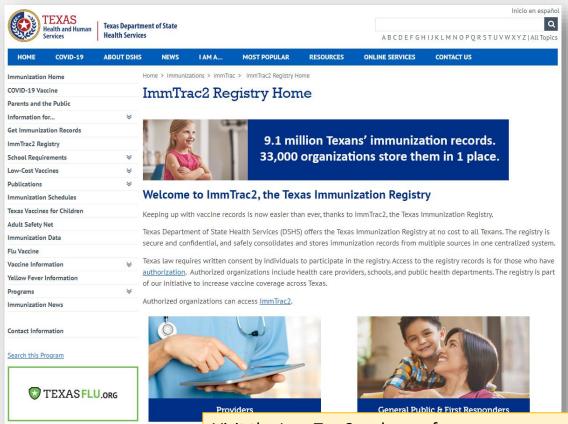
For consent forms and written publications, providers can visit the Forms and Documents webpage at:

https://www.dshs.texas.gov/immunize/immtrac/forms.shtm

Need More Information?

Email: ImmTrac2@dshs.texas.gov

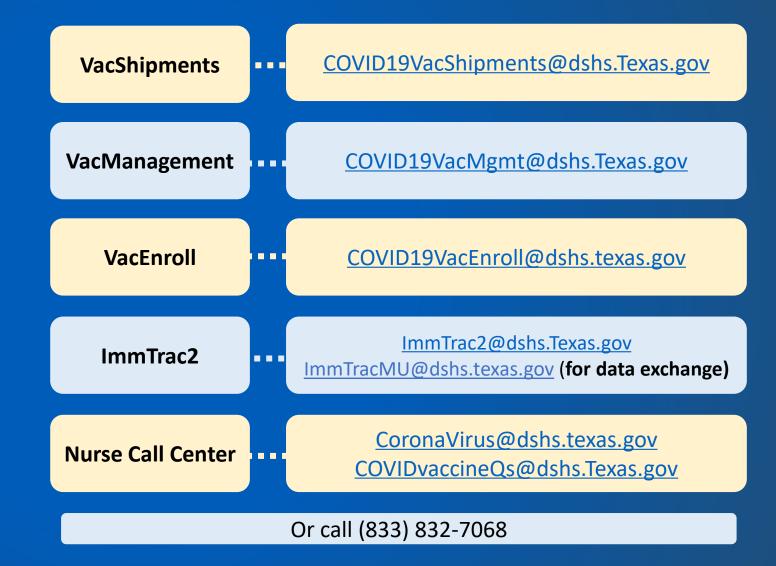
Call: 800-348-9158



Visit the ImmTrac2 webpage for more information about the Texas Immunization Registry, updates, enhancements, and resources:

https://www.dshs.texas.gov/immunize/immtrac/about-immtrac2.aspx

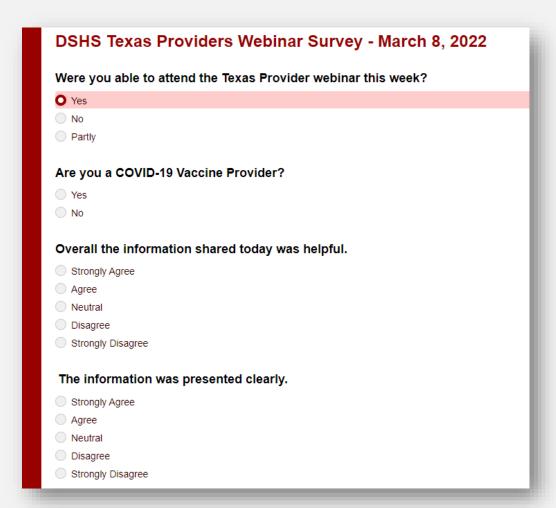
Live Q&A



Texas Vaccine Providers Webinar Survey

We want to hear from you in our Texas Vaccine Providers **Webinar Survey**! This quick survey helps us create content that is relevant and helpful for our Texas providers week over week.

Please complete our <u>post webinar</u> <u>survey</u> for the <u>3/8 Texas Vaccine</u> <u>Providers Webinar</u> by Wednesday, 3/9 at 5:00pm CT.



Resources

Pfizer Medical Affairs-Led Training Events

Goal: Educate providers and immunization staff personnel on the proper use of the Pfizer-BioNTech COVID-19 Vaccine.

Updated Schedule

To access dates and links for upcoming training sessions, please visit:

https://www.pfizermedicalinformation.com/en-us/medical-updates

Session topics include:

- *NEW* Introduction of new Controlant Temperature Monitoring Device
- Use of each vaccine presentation, including storage, handling, preparation, and administration for:
 - Ages 5 through 11 Years: DILUTE BEFORE USE/Orange Cap
 - Ages 12 Years and Older: DO NOT DILUTE/Gray Cap; DILUTE BEFORE USE/Purple Cap
- Recent medical updates regarding the vaccine
- An overview of healthcare provider resources
- Question and answer session

Date & Time	Password
Attendee link – Tuesday, March 8 - 3pm ET	yMMMMnf5U44
Attendee link – Wednesday, March 9 - 12pm ET	2nWpjWa5H8B
Attendee link – Thursday, March 10 - 12pm ET	YMeTxT4qf43
Attendee link – Tuesday, March 15 - 3pm ET	fVJzVYdN326
Attendee link – Wednesday, March 16 - 12pm ET	jEAtpMcM365
Attendee link – Thursday, March 17 - 12pm ET	hwE2sdzwZ53
Attendee link – Tuesday, March 22 - 3pm ET	miSmuZnQ358
Attendee link – Wednesday, March 23 - 12pm ET	iPdKJ8Cia66

Visit Pfizer's webpage for more information about Pfizer led training events: https://www.pfizermedicalinformation.com/en-us/medical-updates

COVID-19 Vaccine Product Availability

When you enter the "doses requested," remember that each COVID-19 vaccine type ships in different pack sizes. Use the table below to determine how many doses to request:

Moderna Pfizer Adult/Adolescent (12+ yrs)		Pfizer Pediatric (5 -11 yrs)		Janssen/J&J		
<100 Doses	>100 Doses	<300 Doses	>300 Doses	<100 Doses	>100 Doses	>100 Doses
Place orders in multiples of 10 doses (1 vial) up to a maximum of 60 doses	Place orders in multiples of 100 doses	Place orders in multiples of 6 doses (1 vial) up to a maximum of 102 doses	Place orders in multiples of 300 doses	Place orders in multiples of 10 doses (1 vial) up to a maximum of 100 doses	Place orders in multiples of 100 doses	Place orders in multiples of 100 doses

Note! As of 10/15/2021, providers placing order requests for more than one COVID-19 vaccine presentation in VAOS will be required to place a *separate order request* for each COVID-19 vaccine presentation they wish to order.

Last Updated: 2/9/2022

COVID-19 Vaccine Provider Support

Call the COVID-19 Provider Support Help Desk at 833-832-7068 Hours of Operation: Monday to Friday, 8 a.m. - 5 p.m. CT

ategory

ole questions

Provider Support Channel

Include in email:

COVID-19 Vaccine Provider Enrollment (Syntropi)

- How to become a COVID-19 Vaccine Provider
- In-progress applications
- Update Enrollment accounts, including population numbers, email addresses, or primary/backup coordinators

Provider Help Desk:

(833) 832-7068 (Option 1) or (877) 835-7750 or Email: COVID19VacEnroll@dshs.te xas.gov

HealthCare Providers/Professionals

https://www.cdc.gov/vaccines/hcp/index.html

Current and new vaccine coordinator name and email address (if new coordinators requested)

COVID-19 Vaccine Provider Information and Safety Reporting

- COVID-19 vaccine safety & medical info
- Administration of vaccine
- Reporting adverse events to VAERS
- Questions/concerns for clinical vaccine considerations

COVID-19 Nurse Call Center:

(833) 832-7068 (Option 4) or Texas 2-1-1 (Option 6), 8 a.m. to 5 p.m., Monday through Friday or Email: CoronaVirus@dshs.texas.go

General Immunization Ouestions:

COVIDvaccineQs@dshs.Texa s.gov

Vaccine Allocation & Ordering System (VAOS)

- Access to VAOS
- Question about completing a task or process in VAOS or dashboards
- Provider Webinars

Covid-19 Vaccine Management:

(833) 832-7068 (Option 2) or Email: COVID19VacMgmt@dshs.Texas.gov

Provider name, org code, and primary and backup vaccine coordinator names and email addresses

Vaccine Distribution & Shipments

- Tracking shipments
- Orders
- Vaccine transfer
- Waste disposal
- Changing inventory in VAOS

Vaccine Shipments:

(833) 832-7068 (Option 2) or Email: COVID19VacShipments @dshs.Texas.gov

For questions about COVID-19 vaccine storage/handling, refer to the <u>manufacturer</u> resources.

Provider name, org code, and service request number or shipment number

Reporting for COVID-19 Vaccines

 Reporting to ImmTrac2 via online web application

ImmTrac2 team:

(833) 832-7068 (Option 3) or (800) 348-9158, 8 a.m. to 4:30 p.m., Monday through Friday or Email: ImmTrac2@dshs.Texas.go v

ImmTracMU for Data Exchange: 800-348-9158 or Email: ImmTracMU@ds hs.texas.gov,

Identification, Disposal, and Reporting of COVID-19 Vaccine Waste

The Operational Summary for the identification, disposal, and reporting of waste has been developed into a webpage for jurisdictions and providers. This page provides information to help awardees and immunization managers identify, handle, dispose of, and report waste in **COVID-19 vaccination programs**. This waste management guidance should not be used for non-COVID-19 vaccines, which are covered under other Centers for Disease Control and Prevention (CDC) vaccination programs. The webpage can be found at the link below:

https://www.cdc.gov/vaccines/covid-19/hcp/wastage-operational-summary.html

COVID-19 Vaccine Waste Guidance

Waste Disposal and Reporting Resources

While it is important to try to use every dose of vaccine possible, that should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

The Texas Commission on Environmental Quality provides guidance on waste disposal:

https://www.tceq.texas.gov/respo nse/covid-19/waste-disposalguidance

For guidance on reporting Moderna doses wasted, see the following guide:

https://www.dshs.texas.gov/immu nize/covid19/Moderna-Wastage-Table-Texas.pdf

Moderna 10/14 COVID-19 Vaccine Wastage Guidance

For guidance on reporting waste in VAOS, see the following guide: https://www.dshs.texas.gov/immu nize/covid19/Waste-in-VAOS.pdf

COVID-19 Vaccine Waste Reporting Waste and Generating Waste Reports in VAOS October 25, 2021

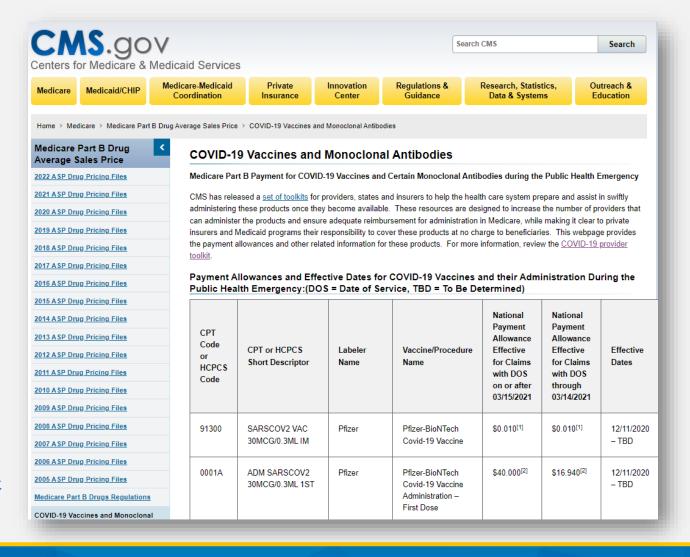
For questions about reporting waste, call (833) 832-7068 (Option 2) or email COVID19VacShipments@dshs.Texas.gov.

Billing Codes

For questions related to billing, visit the Centers for Medicare and Medicaid Services (CMS) resource, which includes CPT codes for COVID-19 vaccines.

CMS COVID-19 Vaccines and Monoclonal Antibodies:

https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies



Ordering COVID-19 Vaccination Record Cards

COVID-19 Vaccine Providers can order additional vaccination record cards.

To order the COVID-19 vaccination record cards, email the following information in the format listed to the COVID-19 Vaccine Provider Help Desk at COVID19VacEnroll@dshs.texas.gov. Please note, *providers* may not exceed 50 cards per request and quantities ordered will be tracked by DSHS.

- Quantity Requested
- PIN:
- Name of facility:
- Point of contact name:
- Address line 1:
- Address line 2:
- City, State, Zip code:

For more information, refer to the email sent from DSHS via GovDelivery on 7/19/2021.

COVID-19 VAOS Job Aids

In the <u>COVID-19 VAOS Job</u>
<u>Aid Catalog</u> you can find all the DSHS job aids you may need as a COVID-19 vaccine provider.

Vaccine Allocation & Order System (VAOS) – Learning Resources

COVID-19 Vaccine Job Aids

- VAOS Tips & Tricks (11/2/2021)
- COVID-19 Vaccine Data Dashboard (6/29/2021)
- COVID-19 Vaccine Product Availability (10/28/2021)
- <u>COVID-19 Vaccine Order Requests in VAOS</u> (10/25/2021)
- Vaccine Transfers in VAOS (10/25/2021)
- VAOS Quick Start Guide (11/19/2021)
- COVID-19 Vaccine Shipments (10/25/2021)
- Reporting Waste in VAOS (10/25/2021)
- Moderna Wastage Table (11/2/2021)
- Generating Reports in VAOS (6/18/2021)

TVFC/ASN Job Aids

- VAOS Quick Start Guide (11/19/2021)
- Open Ordering (10/20/2021)
- Uploading Temperature Logs (10/18/2021)
- Vaccine Shipments (10/18/2021)
- Vaccine Transfers (10/18/2021)
- Entering Doses Administered (10/18/2021)
- Reconciling Physical Inventory (10/18/2021)
- Reporting Waste (10/18/2021)
- Generating Reports (10/18/2021)

COVID-19 Therapeutics Job Aids

- COVID-19
 Therapeutics Job Aid
 (9/24/2021)
- Therapeutics Enrollment Guide (11/10/2021)

VAOS E-Learnings

- COVID-19 Vaccine & Therapeutics VAOS Videos
- TVFC/ASN VAOS Videos

Updated 11/10/2021

COVID-19 Vaccine Fact Sheets

	Pfizer COVID-19 Vaccine (Ages 5-11, Orange Cap)	Pfizer COVID-19 Vaccine (Ages 12+, Purple Cap)	Pfizer COVID-19 Vaccine (Ages 12+, Gray Cap)	Moderna/Spikevax™ COVID-19 Vaccine	Janssen COVID-19 Vaccine
Fact Sheet for Healthcare Providers	https://www.fda.gov/medi a/153714/download	https://www.fda.gov/me dia/153713/download	https://www.fda.gov/media/153715/download	https://www.fda.gov/media/144637/download	https://www.fda.gov/media/ 146304/download
Vaccine Information Fact Sheet for Recipients and Caregivers	https://www.fda.gov/medi a/153717/download	https://www.fda.gov/me dia/153716/download	https://www.fda.gov/media/153716/download	https://www.fda.gov/media/144638/download	https://www.fda.gov/media/ 146305/download
Translations of Fact Sheets for Recipients and Caregivers	https://www.fda.gov/emer gency-preparedness-and- response/coronavirus- disease-2019-covid- 19/comirnaty-and-pfizer- biontech-covid-19- vaccine#translated	https://www.fda.gov/em ergency-preparedness- and- response/coronavirus- disease-2019-covid- 19/comirnaty-and-pfizer- biontech-covid-19- vaccine#translated	https://www.fda.gov/em ergency-preparedness- and- response/coronavirus- disease-2019-covid- 19/comirnaty-and-pfizer- biontech-covid-19- vaccine#translated	https://www.fda.gov/emergency-preparedness- and-response/coronavirus-disease-2019-covid- 19/spikevax-and-moderna-covid-19- vaccine#translated	https://www.fda.gov/emerg ency-preparedness-and- response/coronavirus- disease-2019-covid- 19/janssen-covid-19- vaccine#translated
Other				Important Prescribing Information: https://www.fda.gov/media/153354/download Spikevax package insert: https://www.fda.gov/media/155675/download	

Vaccine Manufacturer Resources



Medical Information

Phone: 800-438-1985

Email:

PfizerMedicalInformation@pfizer.com

Website: <u>www.PfizerMedInfo.com</u>

moderna

Medical Information

Phone: 866-663-3762

Email: MedInfo@modernatx.com

Temperature excursion related

questions:

Email: excursions@modernatx.com



Medical Information

Phone: 800-565-4008

Temperature excursion related questions:

Email:

JSCCOVIDTEMPEXCURSION@its.jnj.com

Disclaimer

The information presented today is based on CDC's recent guidance and MAY change.

Tuesday, March 8, 2022

Thank you!



COVID-19 Vaccines Approved or Authorized in the United States

February 22, 2022

Age		Vaccine Vial Dilution		Primary Series		Booster Dose ^b	
	Indication	Cap Color			Injection Volume	Dose	Injection Volume
Pfizer	5 – 11 years	Orange	Yes	10 mcg	0.2 mL ^a	NA	NA
Pfizer	≥ 12 years	Purple	Yes	30 mcg	0.3 mL	30 mcg	0.3 mL
Pfizer	<u>></u> 12 years	Gray	No	30 mcg	0.3 mL	30 mcg	0.3 mL
Moderna	≥ 18 years	NA	No	100 mcg	0.5 mL	50 mcg	0.25 mL
J&J's Janssen ^c	≥ 18 years	NA	No	5×10 ¹⁰ viral particles	0.5 mL	5×10 ¹⁰ viral particles	0.5 mL

a: Dose based on age at the time of the vaccination

COVID-19 Vaccine Schedule (2/22/22) (texas.gov)



b: Booster doses may be mix and match for individuals >18 yrs, mRNA vaccines are preferred : Booster dose may be mix-and-match vaccine

c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine



COVID-19 Vaccination Schedule

February 22, 2022

	Moderately or Severely Immunocompromised ^a				
	Number of Doses in Primary Series	Number of Booster Doses	Interval between 1 st Dose and 2 nd Dose	Interval between 2 nd dose and 3 rd Dose	Interval between 3 rd Dose and Booster dose ^b
Pfizer (5-11 years) (orange cap)	3	NA	3 weeks	<u>></u> 4 weeks	NA
Pfizer (≥12 years) (purple → gray cap)	3	1	3 weeks	≥ 4 weeks	≥ 3 months
Moderna (≥18 years)	3	1	4 weeks	≥ 4 weeks	≥ 3 months
J&J's Janssen (≥18 years) ^c	1 Dose Janssen, followed by 1 Dose of mRNA vaccine	1	4 weeks	<u>></u> 2 months	N/A

a: A **shorter interval** (3 weeks for Pfizer; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease: COVID-19 Vaccination schedule for people with moderate or severe immunocompromise



b: Booster doses may be mix and match for individuals ≥18 yrs, mRNA vaccines are preferred: Booster dose may be mix-and-match vaccine c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine



COVID-19 Vaccination Schedule

February 22, 2022

	Adults <u>></u> 65 years & Individuals Who Need Rapid Protection ^a					
	Number of Doses in Primary Series	Number of Booster Doses	Interval between 1 st Dose and 2 nd Dose	Interval between 2 nd Dose and Booster Dose ^b		
Pfizer (purple → gray cap)	2	1	3 weeks	<u>></u> 5 months		
Moderna	2	1	4 weeks	≥ 5 months		
J&J's Janssen ^c	1	1	NA	≥ 2 months (between dose 1 and booster dose)		

COVID-19 Vaccine Schedule (2/22/22) (texas.gov)

a: A **shorter interval** (3 weeks for Pfizer; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

b: Booster doses may be mix and match for individuals ≥18 yrs, mRNA vaccines are preferred : Booster dose may be mix-and-match vaccine

c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine





COVID-19 Vaccination Schedule

COVID-19 Vaccine Schedule (2/22/22) (texas.gov)

February 22, 2022

	General Population (Ages 5 - 64 Years) a					
	Number of Doses in Primary Series	Number of Booster Doses	Interval between 1 st Dose and 2 nd Dose	Interval between 2 nd Dose and Booster Dose ^b		
Pfizer (5-11 years) (orange cap)	2	NA	3 weeks ^d	NA		
Pfizer (≥12 years) (purple → gray cap)	2	1	3-8 weeks ^a	≥ 5 months		
Moderna (≥18 years)	2	1	4-8 weeks ^a	<u>></u> 5 months		
J&J's Janssen (≥18 years) ^c	1	1	NA	2 months (between dose 1 and booster dose)		

a: An **8-week** interval may be optimal for some people ages 12 years and older, especially **for males ages 12 to 39 years**. A **shorter interval** (3 weeks for Pfizer; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease: COVID-19 vaccination schedule for the primary series in the general population



b: Booster doses may be mix and match for individuals ≥18 yrs, mRNA vaccines are preferred : Booster dose may be mix-and-match vaccine

c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine

d: Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.